Hearing Date and Time: June 23, 2020, at 10:00 a.m. (prevailing Eastern Time)
Objection Date and Time: June 16, 2020, at 4:00 p.m. (prevailing Eastern Time)

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[1]	**(Jointly Administered)**

NOTICE OF HEARING REGARDING AMENDED MOTION OF DEBTORS FOR AUTHORIZATION TO ENTER INTO FUNDING AGREEMENT

PLEASE TAKE NOTICE that on June 9, 2020, the above-captioned debtors and debtors in possession (collectively, the "**Debtors**") filed the *Amended Motion of Debtors for Authorization to Enter into Funding Agreement* (the "**Motion**"). A hearing on the Motion will be held on **June 23, 2020, at 10:00 a.m. (prevailing Eastern Time)** (the "**Hearing**") before the

[1] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

Honorable Judge Robert D. Drain, United States Bankruptcy Judge, United States Bankruptcy Court for the Southern District of New York, 300 Quarropas Street, White Plains, New York 10601 (the "**Bankruptcy Court**").

PLEASE TAKE FURTHER NOTICE that pursuant to General Order M-543, dated March 20, 2020 (Morris, C.J.) ("**General Order M-543**"), the Hearing will be conducted telephonically.[2] Parties wishing to appear at, or attend, the Hearing must refer to and comply with the Bankruptcy Court's guidelines for telephonic appearances[3] and make arrangements with Court Solutions LLC by telephone at (917) 746-7476.

PLEASE TAKE FURTHER NOTICE that any responses or objections to the Motion shall be in writing, shall conform to the Federal Rules of Bankruptcy Procedure and the Local Bankruptcy Rules for the Southern District of New York, shall be filed with the Bankruptcy Court (a) by attorneys practicing in the Bankruptcy Court, including attorneys admitted *pro hac vice*, electronically in accordance with General Order M-399 (which can be found at www.nysb.uscourts.gov), and (b) by all other parties in interest, on a CD-ROM, in text-searchable portable document format (PDF) (with a hard copy delivered directly to Chambers), in accordance with the customary practices of the Bankruptcy Court and General Order M-399, to the extent applicable, and shall be served in accordance with the *Second Amended Order Establishing Certain Notice, Case Management, and Administrative Procedures* entered on November 18, 2019 [ECF No. 498], so as to be filed and received no later than **June 16, 2020** at **4:00 p.m.** (prevailing Eastern Time) (the "**Objection Deadline**").

[2] A copy of General Order M-543 can be obtained by visiting http://www.nysb.uscourts.gov/news/court-operations-under-exigent-circumstances-created-covid-19.

[3] The Bankruptcy Court's procedures for telephonic appearances are available at: http://www.nysb.uscourts.gov/telephonic-appearances-white-plains.

PLEASE TAKE FURTHER NOTICE that any objecting parties are required to attend the Hearing and a failure to appear may result in relief being granted upon default; *provided* that objecting parties shall attend the Hearing **telephonically** so long as General Order M-543 is in effect or unless otherwise ordered by the Bankruptcy Court.

PLEASE TAKE FURTHER NOTICE that if no Objections are timely filed and served with respect to the Motion, the Debtors may, on or after the Objection Deadline, submit to the Bankruptcy Court an order substantially in the form of the proposed order annexed to the Motion, which order may be entered without further notice or opportunity to be heard.

PLEASE TAKE FURTHER NOTICE that copies of the Motion may be obtained free of charge by visiting the website of Prime Clerk LLC at https://restructuring.primeclerk.com/purduepharma. You may also obtain copies of any pleadings by visiting the Bankruptcy Court's website at http://www.nysb.uscourts.gov in accordance with the procedures and fees set forth therein.

Dated: June 9, 2020
New York, New York

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UNITED STATES BANKRUPTCY COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	**Chapter 11**
PURDUE PHARMA L.P., *et al.*,	**Case No. 19-23649 (RDD)**
Debtors.[4]	**(Jointly Administered)**

AMENDED MOTION OF DEBTORS FOR AUTHORIZATION TO ENTER INTO FUNDING AGREEMENT

[4] The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF LP (0495), SVC Pharma LP (5717) and SVC Pharma Inc. (4014). The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

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Purdue Pharma L.P. ("**PPLP**") and its affiliates that are debtors and debtors in possession in these proceedings (collectively, the "**Debtors**") respectfully state as follows:

Relief Requested

1. By this Motion (the "**Motion**"), and pursuant to sections 105(a) and 363(b) of the United States Code, 11 U.S.C. § 101, *et seq*. (as amended or modified, the "**Bankruptcy Code**"), the Debtors seek entry of an order, substantially in the form attached hereto as **Exhibit A** (the "**Order**"), authorizing the Debtors to enter into an agreement substantially in the form of the Funding Agreement (the "**Agreement**") attached hereto as **Exhibit B** with Harm Reduction Therapeutics, Inc. ("**HRT**").

Jurisdiction and Venue

2. The United States Bankruptcy Court for the Southern District of New York (the "**Court**") has jurisdiction to consider this matter pursuant to 28 U.S.C. §§ 157 and 1334 and the Amended Standing Order of Reference M-431, dated January 31, 2012 (Preska, C.J.). This is a core proceeding pursuant to 28 U.S.C. § 157(b)(2) and, pursuant to Rule 7008 of the Federal Rules of Bankruptcy Procedure (the "**Bankruptcy Rules**"), the Debtors consent to entry of a final order by the Court in connection with this Motion to the extent that it is later determined that the Court, absent consent of the parties, cannot enter a final order or judgment consistent with Article III of the United States Constitution.

3. Venue is proper before the Court pursuant to 28 U.S.C. §§ 1408 and 1409.

General Background

4. On September 15, 2019 (the "**Petition Date**"), the Debtors each commenced with this Court a voluntary case (collectively, the "**Cases**") under chapter 11 of the Bankruptcy Code. The Debtors are authorized to operate their businesses and manage their properties as debtors in

possession pursuant to sections 1107(a) and 1108 of the Bankruptcy Code. On September 27, 2019, the United States Trustee for the Southern District of New York appointed the official committee of unsecured creditors (the "**Committee**"). No trustee or examiner has been appointed in these Cases.

5. Additional information about the Debtors' businesses and the events leading up to the Petition Date can be found in the *Debtors' Informational Brief* filed on September 16, 2019 [ECF No. 17].

Preliminary Statement

6. The Centers for Disease Control and Prevention estimates that, every day, 130 Americans die from opioid overdoses.[5] Some of these deaths could be prevented if individuals, families, first responders and communities had greater access to naloxone, an opioid antagonist "rescue drug" that can counter the effects of an opioid overdose. In nasal spray form, naloxone can be administered by the general public with limited to no training.

7. Intranasal naloxone, sold under the brand name Narcan®, has two fundamental and material barriers to increasing availability: cost and the fact that it is a prescription drug. Narcan retails for $125 or more per twin-pack,[6] a price that creates a significant impediment to wider distribution, especially in communities hardest hit by the opioid crisis.[7] In addition, because Narcan is a prescription drug, patients are often unable or unwilling to go through the process of visiting a doctor and navigating their insurance coverage in order to obtain a

[5] Centers for Disease Control and Prevention, Understanding the Epidemic, https://www.cdc.gov/drugoverdose/epidemic/index.html.

[6] National pharmacies currently quote full retail prices of between $130 and $148. *See* www.goodrx.com/narcan (last accessed 6/5/2020).

[7] *See* Gupta R. et al., *The rising price of naloxone — risks to efforts to stem overdose deaths*, N. Engl. J. Med. 2016; 375:2213–2215, https://www.nejm.org/doi/full/10.1056/NEJMp1609578.

prescription that they then must have filled by a pharmacist. States have attempted to address this concern by enacting legislation or issuing standing orders enabling the sale of naloxone without a prescription.[8] However, even these measures do not adequately clear the barriers to access, as they require individuals to request (sometimes at some embarrassment) the medication from a pharmacist from "behind the counter".[9] As a result of these barriers, the American public's need for naloxone is far from being met.[10]

8. HRT is a non-profit pharmaceutical company, founded in 2017, whose sole mission is to prevent opioid overdose deaths by making a low-cost naloxone nasal spray device (the "**Product**") available over the counter ("**OTC**"). HRT thus seeks to address both barriers to naloxone's availability. First, as a non-profit company, HRT intends to offer millions of doses of its Product at a fraction of the price of Narcan. Second, by bringing to market an OTC naloxone nasal spray, HRT has the potential to greatly increase access. Patients would no longer need to obtain a prescription from their doctor or be required to ask a pharmacist for the drug from "behind the counter." In addition, an OTC naloxone product could be purchased from multiple retailers, or even online, thus lowering an important barrier to availability.

[8] SAFEProject, *State Naloxone Access Rules and Resources*, https://www.safeproject.us/naloxone-awareness-project/state-rules/.

[9] Murphy, S. et al., *Will Converting Naloxone to Over-the-Counter Status Increase Pharmacy Sales?* Health Services Research, 2019; Vol. 54, No. 4, pp. 764–772, 771 ("[M]oving naloxone to OTC would help normalize the purchasing process, and likely reduce concerns of stigma by customers, which would also serve to increase demand.").

[10] *See* Lin, L., Brummett, C.M., Waljee, J.F. et al., Association of Opioid Overdose Risk Factors and Naloxone Prescribing in US Adults, J. Gen. Intern. Med. 35, 420–427 (2020), https://doi.org/10.1007/s11606-019-05423-7 (concluding with respect to naloxone prescriptions that "overall prescribing remains minimal. Additional efforts are needed across health systems to increase naloxone prescribing for patients at risk for opioid overdose.").

9. The resulting increase in naloxone availability could be dramatic. One recent study found that making an OTC naloxone product available could result in a "substantial increase" in naloxone pharmacy sales, potentially as high as 179%.[11]

10. The Food and Drug Administration agrees that greater availability of naloxone would be an important public health advancement and has been actively encouraging drug companies to increase access to naloxone by developing an OTC product.[12] Notably, in January of 2019, the FDA announced that it had developed a model Drug Facts label, which is required for OTC drug products, for both a nasal spray and an autoinjector device, and that the FDA had itself conducted the comprehensive testing that drug companies normally must complete to demonstrate that the instructions on the label are simple to follow.[13] This marks the first time that the FDA has ever proactively developed and tested a Drug Facts label for a drug to support development of an OTC product. The FDA stated that it took this extraordinary step because some potential entrants identified the label design and testing process as a barrier to development.[14] The American Medical Association issued a statement applauding the FDA's

[11] See Murphy et al., supra note 6, at 54:764–772.

[12] *See, e.g.*, U.S. Food and Drug Admin., FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on agency's efforts to advance new ways to increase the availability of naloxone as one means for reducing opioid overdose deaths (Oct. 23, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-efforts-advance-new-ways-increase-availability; U.S. Food and Drug Admin., FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over; U.S. Food and Drug Admin., FDA Statement, Statement on continued efforts to increase availability of all forms of naloxone to help reduce opioid overdose deaths (Sept. 20, 2019), https://www.fda.gov/news-events/press-announcements/statement-continued-efforts-increase-availability-all-forms-naloxone-help-reduce-opioid-overdose.

[13] U.S. Food and Drug Admin., FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on unprecedented new efforts to support development of over-the-counter naloxone to help reduce opioid overdose deaths (Jan. 17, 2019), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-unprecedented-new-efforts-support-development-over.

[14] *Id.*

action and reiterating its strong support for improved access to naloxone.[15] In addition, numerous media sources have reported on the need for improved access to naloxone overdose reversal drugs.[16]

11. HRT is the only organization known by the Debtors to be responding to the FDA's call for an OTC naloxone nasal spray device. And, as explained in greater detail below, Purdue has been HRT's only source of financial support since it began providing financial support to HRT in September of 2018. Purdue's contributions have enabled HRT to make considerable progress. HRT is poised to begin a Phase 1 clinical study that, if successful, will allow it to file a New Drug Application for the Product (the "**NDA**") in early 2021, and expects the Product to be commercially available in early 2022. However, additional resources are required to fund the next stage of development. Without near-term financial support, HRT will be forced to cease operations, potentially on a permanent basis. The Debtors are seeking authority at this time to provide up to $6.5 million of additional funds to HRT, which the Debtors expect would be sufficient for HRT to complete its clinical trials and to sustain HRT's operations through the remainder of 2020.

12. HRT's failure would not benefit any party in these cases. HRT is less than two years away from bringing the Product to market, which would dramatically reduce the current barriers to access to naloxone rescue medication and substantially increase the amount of

[15] American Medical Association, AMA Statement, AMA: FDA action on OTC naloxone will save people from overdoses (Jan. 17, 2019), https://www.ama-assn.org/press-center/ama-statements/ama-fda-action-otc-naloxone-will-save-people-overdoses ("As called for by AMA policy and ongoing advocacy, today's action should spur efforts by naloxone manufacturers to submit applications for their products to receive over-the-counter status. Doing so would be an important step to save even more lives from a national epidemic.").

[16] *E.g.*, Jacquie Lee, *Naloxone Dispensing Is Way Up, but Some Areas Still Lag Behind*, BLOOMBERG LAW (Nov. 26, 2019); Kristen Gerencher, *FDA Urges Broader Access to Naloxone to Avoid Opioid Overdose Deaths*, FORBES (Sept. 25, 2019); Emma Court, *130 Americans Die Each Day from Opioid Overdoses. Experts Are Asking Why a Lifesaving Treatment Isn't Widely Available Without a Prescription*, BUSINESS INSIDER (Sept. 23, 2019).

naloxone rescue medication distributed across the United States. Even by the most conservative estimates, if availability of OTC naloxone reduces the rate of fatal overdoses by just a few percentage points, thousands of lives could be saved every year. Moreover, if HRT is forced to discontinue its efforts, there is no guarantee that another developer will emerge or that another company could deliver a comparable product on the same timeline. The best case scenario if HRT falters would be a substantial delay in the public having access to OTC naloxone. Approval for a $6.5 million investment this year – which is the only relief that the Debtors are seeking at this time – preserves the possibility that OTC naloxone can begin to save lives as soon as early 2022.

13. For the avoidance of doubt, this Motion is not a referendum on the form or content of a plan of reorganization or the size, role or place of public health initiatives in the reorganized Debtors, which have not been agreed amongst any parties, or on any other topic. It is a request to approve the Debtors' business judgment that one half of one percent of the Debtors' cash should be committed to this worthy and critical initiative – a judgment that amply satisfies the governing legal standard under section 363.

Amended Motion

14. On April 1, 2020, the Debtors filed the *Motion of Debtors for Authorization to Enter into Funding Agreement* [ECF No. 1005] (the "**Original Motion**"). Since the filing of the Original Motion, the Debtors have engaged in extensive discussions with the Committee, the Non-Consenting States Group and the ad hoc committee of governmental and other contingent litigation claimants (the "**Ad Hoc Committee**") regarding their concerns relating to the Agreement. The Debtors are filing this amended Motion in an effort to address these concerns.

15. The Debtors have made a number of modifications to the Agreement, which are reflected in this Motion. Most significantly, the Debtors have reduced the relief sought at this time to authorization to make only the first two of the three Milestone Payments (as defined in the Agreement) to HRT, in an aggregate amount of up to $6.5 million (as opposed to the authorization to fund up to $11.5 million to HRT sought in the Original Motion). Of this amount, $2.5 million would be paid upon approval of the Motion, and the remaining $4 million would be paid on or about August 15, 2020, conditioned upon HRT's achieving the Second Milestone Event (as defined below).[17]

16. The Debtors will have no authority to make the Third Milestone Payment (as defined below) without further authorization from the court, which the Debtors may choose to seek in their sole discretion. The modified structure thus offers an "offramp" and opportunity to reevaluate the Agreement at the end of this year. In addition, HRT has agreed to use commercially reasonable efforts to continue to seek additional sources of capital and to clarify that any contributions from a third party would reduce the amount of the Third Milestone Payment on a dollar-for-dollar basis. Finally, in order to accommodate a request from certain of the Debtors' creditors, HRT has agreed that it will return Purdue's prior contributions and that Purdue will be entitled to 20% of HRT's equity interests if HRT later becomes a for-profit entity. To be clear, HRT has informed the Debtors that it has no intention of attempting to become a for-profit company, and as a practical matter the Debtors understand that such a conversion is not possible under applicable law. In addition, the Debtors have revised the proposed form of Order

[17] The Debtors reserve their right to seek further authorization from the Court to make the third and final ($5 million) Milestone Payment at a later date. In the event that the Debtors seek such further authorization, nothing herein is intended to limit or otherwise modify any party's right to object to the granting of such relief on any ground or the Court's evaluation of any such objection.

to emphasize the limited scope of the relief sought in this Motion. Comparisons of the form of Order and the Agreement against the versions filed with the Original Motion are attached hereto as **Exhibit C** and **Exhibit D**, respectively.

The Debtors' Prior Funding of HRT

17. In August of 2018, HRT submitted an initial $3.5 million grant application to Purdue's Office of Corporate Social Responsibility ("**CSR**"). Upon review, CSR considered the amounts that would be required to contribute to development and FDA submission, and recommended approval of a $3.42 million grant. CSR weighed a number of factors, both positive and negative, when conducting its review, including that the request was in line with helping to address the opioid crisis with no expectation of remuneration or financial gain, the need for OTC naloxone and the attendant benefit to enabling HRT to begin work without further delay, the risk that HRT's product might not ultimately be approved, and the risk associated with the need for HRT to raise additional future investment. After receiving the requisite internal approvals, PPLP made this initial $3.42 million unrestricted grant in September 2018. PPLP funded an additional $2.5 million in the ordinary course for further development of the Product in November 2019. In return, HRT affirmed its commitment to manufacture millions of units of the Product so that such units can be donated free of charge or sold at Cost (as defined in the Agreement). For the avoidance of doubt, Purdue has only made the two grants to HRT described in this paragraph, in the aggregate amount of $5.92 million.

HRT Is Well Positioned to Successfully Bring OTC Naloxone to Market

18. HRT's management team has a long and successful history transitioning prescription medications to OTC. Members of the management team have helped develop OTC versions of products such as Nicorette®, Plan B®, Nasacort® Allergy, NicoDerm® CQ®,

Prilosec OTC® and Allegra®, among others. Members of the team also have deep expertise in addiction research and substance abuse treatment.

19. HRT possesses a proprietary preservative-free 3 mg naloxone formulation that is well suited to intranasal delivery. To date, with the Debtors' financial and technical support, HRT has developed an intranasal naloxone formulation, received FDA clearance to proceed with its proposed Phase 1 study, received conditional FDA approval for the Product's trade name, established scientific and advisory boards and identified key vendors, including a contract manufacturer and a sales and distribution vendor. HRT has also conducted Chemistry, Manufacturing, and Control and formulation work, commenced final biocompatibility and other studies, and begun to prepare the Product's NDA. In practical terms, HRT is well positioned to obtain FDA fast-track designation for the Product and for final FDA review and approval of the Product by the end of 2021.

HRT Requires Additional Near-Term Funding

20. The Agreement provides for up to three Milestone Payments in an aggregate amount of $11.5 million, with each payment subject to HRT meeting certain Milestone Events. Under the terms of the Agreement and the proposed Order, the Debtors would have no obligation to make the final Milestone Payment unless, in their sole discretion, they seek (and receive) further authorization from this Court. The Milestone Events and associated Milestone Payments are:

Milestone Event	Milestone Payment	Expected Achievement / Payment Date
Start of Scale-Up Batch at an identified, well-established contract manufacturer (which indicates progress towards formulation development, establishing the Product's stability, and further clinical study) (the "**First Milestone Event**")	$2,500,000	Target completion date: May 1, 2020[18] Payment Date: Three (3) business days after HRT delivers a written notice to PPLP that the First Milestone Event has been met.
Start of Phase 1 Study First Patient In (when testing of the Product with patients begins) (the "**Second Milestone Event**")	$4,000,000	Target completion date: August 15, 2020 Payment Date: Three (3) business days after HRT delivers a written notice to PPLP that the Second Milestone Event has been met.
Completion of Phase 1 Study's Clinical Study Report (which indicates that certain data that is critical to filing an NDA has been collected and provided in the report) (the "**Third Milestone Event**")	$5,000,000	Target completion date: December 31, 2020 Payment Date: Three (3) business days after HRT delivers a written notice to PPLP that the Third Milestone Event has been met; *provided* that the Debtors have, in their sole discretion, sought, and obtained, Court approval to make such payment.

21. The timing and amount of the Milestone Payments are structured such that the amount of each Milestone Payment is sufficient only to bridge HRT to the next Milestone Event. HRT does not maintain excess cash or a line of credit that could provide a cushion in the event that the Debtors do not or cannot make an anticipated Milestone Payment.

[18] Milestone Event has been achieved.

22. And funding is needed now. Without the First Milestone Payment, HRT's accounts will be empty by the end of July. Even leaving aside the fact that delay of the development timeline would delay the launch of a life-saving medication, HRT cannot simply "push pause" pending additional funding and resume work months from now. The company relies on third-party vendors to develop the Product, and failure to pay these vendors would result in breached contracts and fractured working relationships. HRT's employees, many of whom are highly credentialed and already work at a discount in furtherance of HRT's nonprofit mission, would also likely explore other opportunities, which would further hinder the development and ultimate availability of low-cost naloxone.

23. Moreover, HRT could not continue its clinical development work if the Court authorizes the Debtors to make the First Milestone Payment but not the Second Milestone Payment because both payments are required to finance a key upcoming clinical trial. HRT is preparing to commence a Phase 1 Study in August to evaluate the Product's safety and absorption to ensure it will be effective in reversing overdoses in the real world. This is a trial involving healthy volunteers that will last several months. Without the Second Milestone Payment, HRT would not have sufficient funds to complete the study. In practice, it would be irresponsible for a pharmaceutical company to commence such a trial with such uncertainty regarding its ability to finish it. If there were substantial risk regarding access to future funding, the company could not ensure that funds would be available to conduct safety follow-ups of subjects who have been dosed in the study. In other words, HRT cannot commence the Phase 1 Study in August without certainty that the Debtors will be able to make the Second Milestone Payment. And delaying the Phase 1 Study would create a material risk to HRT's operations, due to the serious risk that HRT would never be able to recover from a temporary shutdown.

If the Motion Is Denied, HRT Is Unlikely to Secure Timely Alternative Financing

24. The Debtors have been the only material source of funding for HRT to date, despite HRT's efforts to obtain financial support from dozens of charitable foundations, high-net-worth individuals, and other potential funders. There are at least five factors that help explain HRT's lack of additional outside funding sources to date despite the many voices supporting its life-saving mission. First, drug development is expensive, and only the largest philanthropies have the capacity to contribute millions of dollars of capital. There are no large non-profit or charitable organizations (e.g., the American Cancer Society, which gathers donations for cancer research and therapies) dedicated to supporting the development of rescue drugs. Many smaller organizations and high-net-worth individuals, who often have a larger number of worthy causes to evaluate than funds to offer, have expressed a concern that a donation of a few thousand dollars to HRT would not be material given HRT's needs. Second, most philanthropic organizations are accustomed to funding drug distribution (e.g., anti-malarial medicines) but not to the regulatory and scientific complexity inherent in the highly technical process of drug development. The lack of pharmaceutical development subject matter expertise within philanthropic organizations makes it particularly difficult for these organizations to evaluate potential contributions to HRT. Third, there is very little precedent for nonprofit pharmaceutical companies. To the Debtors' knowledge there are currently only two other nonprofit pharmaceutical companies with any drug development experience, Medicines360, which is focused exclusively on women's health, and CivicaRx, a nonprofit producing drugs to address the in-hospital drug shortage crisis, neither of which is at all involved with developing overdose reversal products. The lack of precedent adds a further element of uncertainty to any decision by a philanthropic organization to provide financial support to HRT. Fourth, many of

the largest philanthropic organizations (e.g., the Bill and Melinda Gates Foundation, the Open Society Foundations) have a global focus, rendering U.S.-centric efforts less attractive to them. Fifth, there are limited opportunities for direct support from state or federal agencies.

25. The Debtors appreciate the importance of OTC naloxone from a public health perspective and are uniquely positioned to provide financial support to HRT. As a pharmaceutical company with sophistication in drug development, the Debtors understand the regulatory and scientific complexity associated with HRT's mission and appreciate the value of HRT's unparalleled experience transitioning prescription medications to OTC. The Debtors have the financial wherewithal to make a multi-million dollar contribution and are not limited by competing charitable demands or geographic scope in the same way that philanthropic organizations may be. Moreover, there is no expectation that a contribution to HRT would ever be paid back, which makes it unlikely that other for-profit pharmaceutical companies will be interested in lending their support.

The Relief Requested Is Limited in Scope

26. As discussed above, if this Motion is granted, the Debtors will be obligated to fund a maximum of $6.5 million under the Agreement, which will enable HRT to complete the upcoming Phase 1 Study to evaluate the Product's safety and efficacy. That is the extent of the requested relief. The Debtors will have no obligation to make the Third Milestone Payment or advance any other amounts whatsoever absent further order of the Court, nor will they be obligated to conduct any future commercialization activities or purchase any Product. In the event that the Debtors do seek authorization to provide any additional support, this Motion and the relief sought herein will not limit any party's right to object on any ground. Moreover, the Debtors are free to assign their commitment to any other party, and if HRT receives any funding

from any third party to develop the Product prior to the Third Milestone Payment having been made, such funding will reduce the amount of the Third Milestone Payment dollar-for-dollar.

27. The Debtors believe that the availability of the Product in the United States would save thousands of lives per year. The Debtors further hope to be able some day to fund the provision of millions of doses of the Product for free or at cost. That said, as noted above, this Motion is not a referendum on the form or content of a plan of reorganization, the size, role or place of public health initiatives in the reorganized Debtors, or any other topic. Rather, the Debtors are seeking authorization to use one half of one percent of their cash to advance development of a vitally important rescue medication.

28. The negotiation of the terms of the Agreement was conducted at arm's length.

HRT Is an Independent Non-Profit Whose Sole Mission Is to Prevent Overdose Deaths

29. HRT was co-founded by John Pinney and Michael Hufford in 2017. Mr. Pinney is the Chairman of the Board of HRT and is also the founder and Chief Executive Officer of Pinney Associates, a consulting firm providing scientific, regulatory and policy services to the pharmaceutical industry. Pinney Associates focuses on three main business units: prescription drug strategic services, OTC strategic services (which includes the Rx-to-OTC switch business from which HRT draws its expertise) and tobacco harm reduction. Purdue has engaged Pinney Associates from time to time for various projects since 2001.

30. The Debtors anticipate that some creditors may assert that because Pinney Associates performed services for Purdue in years past, HRT should not receive funding from the Debtors now, no matter how laudable HRT's goals or how many thousands of lives could be saved. The Debtors do not agree that HRT has forfeited its right to do good work with the

Debtors' support because of its association with Pinney Associates, and Pinney Associates' prior association with the Debtors.

31. HRT is not Pinney Associates and is not owned by Pinney Associates. Pinney Associates will not profit from HRT's success. Under Maryland law, HRT is prohibited from having any stockholders, and HRT's articles of incorporation provide that no part of the net earnings of the company shall inure to the benefit of or be distributed to any director or any other private person, except that HRT is authorized to pay reasonable compensation for services rendered and to make payments and distributions in furtherance of its charitable and/or public benefit purposes. Section 4.2(A) of the Agreement contains a representation, warranty and covenant from HRT to PPLP that reaffirms these restrictions in HRT's organizational documents. While HRT employs certain Pinney Associates employees as consultants, it generally pays a discounted rate for those individuals' services, and John Pinney personally receives no compensation for any work he performs for HRT.

32. Michael Hufford, HRT's Chief Executive Officer, brings 20+ years of clinical research and drug development experience to HRT, with a consistent track record of achieving clinical development milestones, including FDA approval. Dr. Hufford was Vice President, Regulatory Affairs, Behavioral Science & Innovation at Pinney Associates from 2015 to 2018 and is not currently a Pinney Associates employee.

33. Pinney Associates, an entirely separate company from HRT, has performed various consulting services for Purdue since 2001. The individual projects on which Pinney Associates consulted were limited in duration and scope. Between 2002 and 2018, a period of sixteen years, the Debtors paid Pinney Associates an aggregate amount of approximately $3.97

million. Likewise, between 2001 and 2019, the Debtors understand that engagements with Purdue generated less than 3% of Pinney Associates' total revenues.

34. But even if Pinney Associates' prior work for Purdue was not limited, that would not disqualify HRT from receiving support from the Debtors to develop an FDA-requested, potentially life-saving rescue drug under an Agreement that commits the Debtors to fund $6.5 million and provides for appropriate milestones and offramps. Indeed, at the hearing to consider the nalmefene autoinjector motion the Court rejected a similar objection previewed by the Non-Consenting States Group, noting that, while "history does matter here . . . as everyone recognizes, the value in this company should be put to good use." Hr'g Tr. 33:7-13 (Feb. 21, 2020).

35. The same applies here. There is an opportunity today to put Purdue's assets to good use. While Purdue has agreed that this Motion should not constitute a step on any particular path for these Cases, neither should it be an opportunity to derail development of a potentially valuable tool in fighting the epidemic of opioid overdose deaths.

36. Critically, the Debtors are confident that HRT will bring the Product to market and understand that no other company is working on an OTC naloxone rescue drug. The Debtors are aware of efforts to launch a generic form of naloxone. However, this generic product would still be prescription, not OTC, and would be sold for profit. A prescription generic product would not adequately address the fundamental barriers to access that prescription solutions present.

Basis for Relief Requested

37. Bankruptcy Code section 363(b)(1) empowers the Court to authorize a debtor to "use, sell, or lease, other than in the ordinary course of business, property of the estate." To

approve the use of estate property under section 363(b)(1) of the Bankruptcy Code, the Second Circuit requires a debtor to show that the decision to use the property outside of the ordinary course of business was based on the debtor's sound business judgment in light of "all salient factors" relating to the bankruptcy case. *Comm. of Equity Sec. Holders v. Lionel Corp. (In re Lionel Corp.)*, 722 F.2d 1063, 1070-71 (2d Cir. 1983) ("The rule we adopt requires that a judge determining a § 363(b) application expressly find from the evidence presented before him at the hearing a good business reason to grant such an application."); *In re Ionosphere Clubs, Inc*., 100 B.R. 670, 675 (Bankr. S.D.N.Y. 1989); *see also In re MF Global Inc*., 467 B.R. 726, 730 (Bankr. S.D.N.Y. 2012) ("Although not specified by section 363, the Second Circuit requires that transactions under section 363 be based on the sound business judgment of the debtor or trustee.").

38. Section 105(a) of the Bankruptcy Code provides that the "court may issue any order, process, or judgment that is necessary or appropriate to carry out the provisions of this title." 11 U.S.C. § 105(a). Pursuant to section 105(a), orders are appropriate where they are essential to the debtor's reorganization efforts and do not pose a burden on the debtor's creditors. *See U.S. Lines, Inc. v. Am. S.S. Owners Mut. Prof. & Indem. Ass'n (In re U.S. Lines, Inc.)*, 197 F.3d 631, 640 (2d Cir. 1999); *Momentum Mfg. Corp. v. Emp. Creditors Comm. (In re Momentum Mfg. Corp.)*, 25 F.3d 1132, 1136 (2d Cir. 1994) ("It is well settled that bankruptcy courts are courts of equity, empowered to invoke equitable principles to achieve fairness and justice in the reorganization process.").

39. Under the unusual circumstances of these Cases, the "salient factors" considered when evaluating the Debtors' business judgment, and whether the Debtors' decision to fund HRT's efforts would aid the Debtors' reorganization, must include how funding HRT would

benefit all of the Debtors' contingent creditors and the American public at large. The Court has previously observed that "the Debtors' cases are highly unusual" in that "the Debtors are largely in a [sui generis] position whereby they have already agreed to turn over all of their value to their creditors," Hr'g Tr. 159:16-19 (Nov. 19, 2019), and that "this is a fundamentally public health crisis driven case where the claimants, in one sense, can be almost every citizen in the country." Id. at 159:9-12. As a result, the Court concluded that it should consider "how the public at large is to benefit" from a request by the Debtors to use property outside of the ordinary course of business. Id. at 160:17-20.

40. The Court was perfectly clear at the most recent hearing in these Cases that "what is unusual about this case is that there is ongoing harm" being suffered by individuals and the governments that serve them. Hr'g Tr. 94:11-17 (Jun. 3, 2020). The Court further cautioned that "[I]f I hear a month or two from now that people cannot set aside their views as to what is the perfect use for the money that is available here and agree to share on how that is to be used, I will be taking steps to move the case along separately, and it's shame on us if we don't do that. This is flesh and blood." *Id*. at 95:11-16.

41. The Debtors' decision to fund HRT's development of OTC naloxone is a sound exercise of the Debtor's business judgment and will hopefully facilitate and progress an initiative that could save thousands of lives. As discussed above, development of an OTC naloxone product is strongly encouraged by the FDA and the American Medical Association and broadly supported by academic studies. Moreover, only one company – HRT – is presently working towards bringing this life-saving product to market.

42. Since September of 2018, the Debtors have continued to provide modest but vital financial support to HRT in an effort to advance meaningful solutions to the opioid crisis.

Purdue made its initial decision to fund HRT, and its later decisions to provide additional funding, after careful evaluation of, among other things, the critical need for OTC naloxone, the close fit between HRT's and Purdue's CSR goals, detailed supporting budgets and development timelines, Purdue's own financial position, and HRT's capabilities and prospects of success. Before making each additional contribution to HRT, Purdue carefully evaluated HRT's progress toward bringing OTC naloxone to market, and how Purdue's contribution would allow HRT to achieve concrete milestones on the path to that goal. The Debtors' sophistication in pharmaceutical development also informed their assessment of HRT's funding proposals and the structure of the resulting funding agreements.

43. Based on HRT's progress to date and need for additional funding, the Debtors now seek authority to provide up to $6.5 million of additional funding to HRT. The amount requested is based on a detailed budget and timeline, and the Debtors' obligation to make the $4 million Second Milestone Payment under the Agreement is contingent on HRT reaching an important milestone in the development of OTC naloxone. Moreover, the Agreement will not commit the Debtors to provide any future support after the Second Milestone Payment, financial or otherwise, in respect of the Product. Due to the nature of the Agreement and the amount of the funding requested herein, the Debtors also sought (and received) authorization from their Board of Directors. And, after filing the Original Motion, the Debtors continued to discuss the terms of the Agreement with major creditor groups, which resulted in the further modifications discussed in this Motion. In sum, the Agreement contains appropriate safeguards and limitation for a grant of this type, received all requisite internal approvals, and reflects the Debtors' considered judgment.

Debtors' Reservation of Rights

44. Nothing contained herein or any action taken pursuant to such relief is intended or shall be construed as (a) an admission as to the validity or priority of any claim against the Debtors; (b) a waiver of the Debtors' or any appropriate party in interest's rights to dispute the amount of, basis for or validity of any claim against the Debtors; (c) a waiver of any claims or causes of action which may exist against any creditor or interest holder or any other party; or (d) an approval, assumption, adoption or rejection of any agreement, contract, lease, program or policy between the Debtors and any third party under section 365 of the Bankruptcy Code. Likewise, if the Court grants the relief sought herein, any payment made pursuant to the Court's order is not intended to be and should not be construed as an admission as to the validity or priority of any claim or a waiver of the Debtors' rights to subsequently dispute such claim.

Waiver of Stay Under Bankruptcy Rule 6004(h)

45. The Debtors also request that, to the extent applicable to the relief requested in this Motion, the Court waive the stay imposed by Bankruptcy Rule 6004(h), which provides that "[a]n order authorizing the use, sale, or lease of property other than cash collateral is stayed until the expiration of 14 days after entry of the order, unless the court orders otherwise." Fed. R. Bankr. P. 6004(h). As described above, the relief that the Debtors seek in this Motion is necessary for the Debtors to maximize the value of their estates. Accordingly, the Debtors respectfully request that the Court waive the 14-day stay imposed by Bankruptcy Rule 6004(h), as the nature of the relief sought herein justifies immediate relief.

Notice

46. Notice of this Motion will be provided as to (a) the entities on the Master Service List (as defined in the *Second Amended Order Establishing Certain Notice, Case Management,*

and Administrative Procedures entered on November 18, 2019 [ECF No. 498] and available on the Debtors' case website at https://restructuring.primeclerk.com/purduepharma) and (b) any person or entity with a particularized interest in the subject matter of this motion (the "**Notice Parties**"). The Debtors respectfully submit that no further notice is required.

No Prior Request

47. The Debtors have not previously sought the relief requested herein from the Court or any other court.

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WHEREFORE, the Debtors respectfully request that the Court enter the proposed form of order, substantially in the form attached hereto, granting the relief requested herein and such other relief as the Court deems appropriate under the circumstances.

Dated: June 9, 2020
New York, New York

DAVIS POLK & WARDWELL LLP

By: */s/ Marshall S. Huebner*

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